UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LOIS RONCAL; JOHN NATHAN TIMM; BOBBIE ROBERTS; TROY ROBERTS; JENNIFER GRANBERRY, *Personal Representative of the Estate of LINDALE GRANBERRY*; CYNTHIA SKILES; RAYMOND SKILES; FRANK TRICOMI, JR; MARILYN TRICOMI; JOHN POTOSNAK, III; VAILE POTOSNAK; ROBERT GHISELIN; GERI GHISELIN; CONNIE LUYE, *Personal Representative of the Estate of EVELYN MOSS*; FERNANDO CASTELLANOS; MICAELA CASTELLANOS; JIMMY TOLBERT; IMOGENE BERRY; FRANCIS DODD; CONSTANCE JAMES, *Personal Representative of the Estate of GEORGE NOBLIN*, Plaintiffs, v. AUROBINDO PHARMA USA, INC.; and DOES 1-50, *Inclusive*, Defendants.	Civil Action No. 3:20-cv-02643

OPINION

Plaintiffs allege that they, their spouses, or the decedents they represent were injured or died as a result of having taken Amiodarone to treat non-life-threatening atrial fibrillation ("a-fib"), at least some of which was manufactured by Defendant Aurobindo USA, Inc. Plaintiffs bring seven claims: (1) Strict Products Liability – Failure to Warn, (2) Negligence – Failure to Warn, (3) Negligence – Marketing and Sale, (4) Negligence

Per Se, (5) Strict Liability – Manufacturing Defect, (6) Fraud and Deceit, and (7) Wrongful Death. See ECF No. 26 ("SAC") ¶¶ 112-75. The Court has jurisdiction over these claims pursuant to 28 U.S.C. § 1332.

Aurobindo moves to dismiss Plaintiff's Second Amended Complaint ("SAC") pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. ECF No. 27. For the reasons set forth below, Aurobindo's motion will be granted.

I[1]

A

In 1985, non-party Wyeth obtained Food and Drug Administration ("FDA") approval to market and sell Cordarone "as a drug of last resort for patients suffering from documented, recurrent, life-threatening, ventricular fibrillation and ventricular tachycardia when the[] conditions would not respond to other available anti-arrhythmic drugs and therapies." SAC ¶ 31; see also SAC ¶¶ 57, 100, 105. Cordarone "was never approved . . . for the treatment of [a-fib] that Plaintiffs suffered from." SAC ¶ 31. Aurobindo manufactures Amiodarone, a generic version of Cordarone. SAC ¶¶ 28, 30.

Wyeth "and others" marketed Cordarone as a "first line anti-arrhythmic therapy," including for treatment of a-fib. SAC ¶ 32. The FDA warned Wyeth that it is "unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug." SAC ¶ 32; see also SAC ¶¶ 58 (describing other "enforcement actions"

[1] The following allegations are accepted as true for purposes of Aurobindo's motion. See, e.g., Bruni v. City of Pittsburgh, 824 F.3d 353, 360 (3d Cir. 2016).

taken against Wyeth "regarding the marketing and labeling of Cordarone" from 1986 to 2004), 59, 61, 63-69, 71-74.

Plaintiffs allege that Aurobindo benefitted from Wyeth's off-label promotional efforts by "focusing primarily on pricing in their marketing and promotional efforts to increase market share." SAC ¶¶ 32, 85, 94, 135-37, 161.

Plaintiffs also allege that Aurobindo misled doctors and the public. To that end, Plaintiffs assert that Aurobindo and others "directly or indirectly provided the indications and usage information regarding Amiodarone to the distributor of the Physician's Desk Reference . . . and the developer of Epocrates, the two most widely used reference materials used by physicians in prescribing situations." SAC ¶ 33. The information about Amiodarone in reference material such as Epocrates allegedly "deceives physicians into believing" Amiodarone is approved for treatment of a-fib, is not a drug of last resort to be used in limited situations, has benefits that outweigh its safety risks with respect to a-fib, and "underwent appropriate FDA-approved randomized, clinical trials." SAC ¶¶ 36, 39; see also SAC ¶¶ 37-39. Aurobindo licensed pictures of its Amiodarone pills to Epocrates. SAC ¶¶ 40, 140.

Plaintiffs' allegations are predicated on Aurobindo's alleged failure to provide warnings and information about its product. Plaintiffs allege that Aurobindo failed to fulfill its obligations regarding Medication Guides. See SAC ¶¶ 44-45. Medication Guides are "FDA-approved patient labeling," 21 C.F.R. § 208.3(h), that must be written "in nontechnical, understandable language," describe "the particular serious and significant public health concern that has created the need for the Medication Guide," 21

C.F.R. § 208.20(a)(1), (b)(2), and be provided to patients or their agents barring an applicable exception, see 21 C.F.R. § 208.24. Like other manufacturers, Aurobindo is required to ensure that Medication Guides are available for distribution to patients prescribed Amiodarone. See SAC ¶¶ 1-16 (subparagraph b), 44, 51; 21 C.F.R. §§ 208.1, 208.24. Plaintiffs allege that Aurobindo failed to: (1) provide Medication Guides to Plaintiffs, see, e.g., SAC ¶¶ 1-16 (subparagraph f), 21, 44, 88, 111, 114, 145, 147; (2) provide sufficient numbers of Medication Guides or provide them "in proper form," see SAC ¶¶ 1-16 (subparagraph e), 20, 44, 48-49, 104, 110-11; and (3) ensure Plaintiffs received the Guides, see SAC ¶¶ 1-16 (subparagraph f), 44, 51, 104, 110-11. Plaintiffs contend that Aurobindo's failures in this regard also render Amiodarone a mislabeled drug under New Jersey law. SAC ¶¶ 44-45, 51.

Plaintiffs additionally claim that Aurobindo knew of adverse events and risks related to Amiodarone but failed to report them. SAC ¶¶ 47, 56, 76, 90-94. For example, Plaintiffs allege that "Amiodarone . . . has become the number one prescribed drug for the treatment of" a-fib, and that "there would be tens of thousands o[f] adverse event reports submitted [to the FDA] each year" given "the percentages of persons diagnosed with just pulmonary toxicity," yet there "appear" to be far fewer adverse event reports submitted to the FDA. SAC ¶ 79; see also SAC ¶¶ 81-84, 118-21.

B

Aurobindo has moved to dismiss the SAC. ECF No. 27. Plaintiffs oppose the motion. ECF No. 30. This matter was assigned to the undersigned for the limited purpose of resolving the motion to dismiss. ECF No. 35.

II[2]

A

At the outset, the Court addresses the governing law. Although Plaintiffs argue that they plead violations of New Jersey law "in the alternative," their argument is belied by their allegations. ECF No. 30 ("Pls' Op.") at 2. Plaintiffs repeatedly allege that Defendants' conduct violated New Jersey (and federal) law. See SAC ¶¶ 1-16 (subparagraph e), 44-45, 51, 96, 128, 147-48, 157. The SAC mentions the law of no other state, and the SAC's allegations do not suggest New Jersey law was plead alternatively. See id.

"A federal court sitting in diversity applies the choice-of-law rules of the forum state—here, New Jersey—to determine the controlling law." Maniscalco v. Brother Int'l (USA) Corp., 709 F.3d 202, 206 (3d Cir. 2013). New Jersey has adopted "the Second Restatement's most-significant-relationship test . . . for deciding the choice of substantive law in tort cases involving more than one state." McCarrell v. Hoffmann-La Roche, Inc., 153 A.3d 207, 219 (N.J. 2017) (emphasis omitted). This test requires a court to examine, among other things, "whether or not an actual conflict exists between the laws of the

[2] When examining whether a complaint should be dismissed under Rule 12(b)(6), a court must determine whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In evaluating plausibility, courts "disregard rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements." James v. City of Wilkes-Barre, 700 F.3d 675, 679 (3d Cir. 2012). A claim "has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Thompson v. Real Est. Mortg. Network, 748 F.3d 142, 147 (3d Cir. 2014).

potential forums." Maniscalco, 709 F.3d at 207. A party seeking to apply the law of a foreign jurisdiction has the burden to show such law applies. See Chernus v. Logitech, Inc., No. 17-CV-00673, 2018 WL 1981481, at *10 (D.N.J. Apr. 27, 2018) (relying on Maniscalco and stating that "in examining which law applies, [plaintiff] would have to demonstrate, first, that California law has the most significant relationship to his individual claims"); see also Guy Mitchell & Betty J. Mitchell Fam. Tr. ex rel. Stanzak v. Artists Rts. Enf't Corp., No. 11-CV-0024, 2014 WL 202099, at *2 (E.D. Wash. Jan. 17, 2014) ("AREC fails to uphold its burden, as the party seeking to apply foreign law, to show that an actual conflict exists between New York and Washington law."), aff'd sub nom. Mitchell v. Artists Rts. Enf't Corp., 653 F. App'x 522 (9th Cir. 2016); Triple Int., Inc. v. Motel 6, Inc., 414 F. Supp. 589, 594 (W.D. Wis. 1976) (explaining, in the context of a contract dispute, that "the party urging application of the foreign law must show the more significant relationship of the foreign state to the transaction and to the parties").

To the extent Plaintiffs argue that the Court should apply the law of their states of residence, they have not identified whether those laws conflict with the forum's law. See Pls.' Br. at 8-9 (noting this step of the test and identifying no conflicts).[3] Given Plaintiffs' failure to identify a conflict, the law of the forum governs. See, e.g., Gelis v. Bayerische Motoren Werke Aktiengesellschaft, No. 17-CV-07386, 2018 WL 6804506, at *4 (D.N.J. Oct. 30, 2018) ("[W]here the parties fail to point out or establish any

[3] The only pertinent foreign state laws mentioned in Plaintiffs' brief are the learned intermediary doctrines of Texas and Illinois, which they assert do not bar their claims, Pls.' Br. at 23-25, but they do not explain how, if it all, the doctrine in those states conflicts with New Jersey's learned intermediary doctrine.

difference in the laws of the various jurisdictions involved in a particular case, it is proper for the court to apply the law of the forum." (quotation marks and citation omitted)).[4] Accordingly, New Jersey law applies.

B

Having determined that New Jersey law applies, the Court next addresses which New Jersey law applies. Plaintiffs have alleged seven common law claims. Aurobindo argues that the New Jersey Products Liability Act ("PLA"), N.J.S.A. § 2A:58C-1, et seq., subsumes those common law claims and thus all of Plaintiffs' common law claims must be dismissed. In response, Plaintiffs now contend that their "claims should be fairly read as alleging violations of the" PLA "[t]o the extent . . . New Jersey law controls," Pls.' Br. at 12, and offer to replead if needed. As discussed below, the PLA does control, but repleading is not needed because the Court will construe Plaintiffs' allegations as if lodged under the PLA.

[4] Additionally, as a general matter, the Second Restatement provides that, "[i]n an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties, in which event the local law of the other state will be applied." Restatement (Second) of Conflict of Laws § 146 (1971). Plaintiffs have alleged only their residence and did not allege where their injuries occurred. Thus, they have failed to provide the facts needed to identify the state law that may apply. For this additional reason, the Court applies New Jersey law. Chernus, 2018 WL 1981481, at *8 n.6 ("[T]he parties have not briefed this issue and have not presented sufficient facts for the Court to make the necessary findings. It is well-recognized that courts cannot meaningfully engage in a choice-of-law analysis absent a factual record; to do so would be entirely speculative.").

"[T]he PLA codified certain issues relating to the common law governing product liability actions."[5] Sun Chem. Corp. v. Fike Corp., 235 A.3d 145, 152 (N.J. 2020). In doing so, "[t]he [PLA] left intact the three theories under which a manufacturer or seller may be held strictly liable for harm caused by a product—defective manufacture, defective design, and defective warnings." Roberts v. Rich Foods, Inc., 654 A.2d 1365, 1370 (N.J. 1995) (quotation marks omitted). "If a claim is premised upon a product's manufacturing, warning, or design defect, that claim must be brought under the PLA." Sun Chem. Corp., 235 A.3d at 155; see also In re Lead Paint Litig., 924 A.2d 484, 503 (N.J. 2007) ("The language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products."). Thus, "the []PLA generally subsumes common law product liability claims," making the PLA "the sole basis of relief under New Jersey law available to consumers injured by a defective product." Repola v. Morbark Indus., Inc., 934 F.2d 483, 492 (3d Cir. 1991).

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[5] The PLA provides:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. § 2A:58C-2.

Plaintiffs' claims are based on theories that they were harmed by the failure to provide a warning, the deficiency of product warnings and information in reference materials, and the failure to disclose adverse events related to the product. See SAC ¶¶ 125-69. Because each theory is predicated on a failure to warn, each is subsumed by the PLA and subject to dismissal. See Sun Chem. Corp., 235 A.3d at 155 (explaining that "claim[s] . . . premised upon a product's manufacturing, warning, or design defect[] . . . must be brought under the PLA"); see N.J.S.A. § 2A:58C-1(b)(3) (defining a "[p]roduct liability action as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty"); see also Hindermyer v. B. Braun Med. Inc., 419 F. Supp. 3d 809, 821-22 (D.N.J. 2019) (collecting cases discussing fraud claims sounding in products liability that were subsumed by the PLA); Brown ex rel. Est. of Brown v. Philip Morris Inc., 228 F. Supp. 2d 506, 516 (D.N.J. 2002) (collecting cases).

Although a plaintiff can "avoid [PLA] subsumption" by "assert[ing] a negligence claim that arises from the independent conduct of a defendant, which is unrelated to the inherent defect in the product, itself," Plaintiffs have not done so here. Hindermyer, 419 F. Supp. 3d at 823. Accordingly, notwithstanding Plaintiffs' "attempt[] to shoehorn [their] allegations into other causes of action, it is clear" that Plaintiffs' negligence and fraud claims (Counts 2, 3, 4, and 6) "sound in products liability causes of action" and must be dismissed. Barrett v. Tri-Coast Pharmacy, Inc., 518 F. Supp. 3d 810, 824 (D.N.J. 2021); see Medford v. Eon Labs, Inc., No. 20-CV-00412, 2021 WL 5204035, at *3 n.3 (D.N.J. Nov. 9, 2021) (dismissing, in Amiodarone case, plaintiffs' claims "to the extent

. . . [they] assert[] negligence claims under New Jersey law and . . . consumer fraud claims under the New Jersey Consumer Fraud Act" because they were "subsumed by the [PLA]").[6] We will construe Plaintiffs' strict liability claims (Counts 1 and 5) as if pleaded under the PLA and examine whether they state claims upon which relief can be granted.

III

Plaintiffs' PLA claims are either preempted, inadequately plead, or both. The preemption doctrine stems from the Supremacy Clause of the Constitution, which

[6] Even if Plaintiffs' negligence and fraud claims were not subsumed by the PLA, they would fail for the same reasons that the PLA failure-to-warn claim fails. In addition, Plaintiffs' off-label promotion claims (1) are inadequately plead, as they fail to allege sufficient facts as to Aurobindo's promotional activities, and (2) are "subject to preemption under Buckman . . . 'because the duties [plaintiffs allege [Aurobindo]] breached regarding off-label promotion exist solely under the [Food, Drug, and Cosmetic Act].'" Frei v. Taro Pharms. U.S.A., Inc., 443 F. Supp. 3d 456, 468-69 (S.D.N.Y. 2020) (quoting Bean v. Upsher-Smith Pharm., Inc., No. 4-16-cv-01696, 2017 WL 4348330, at *7 (D.S.C. Sept. 29, 2017) (first alteration in original), aff'd, 765 F. App'x 934 (4th Cir. 2019)), aff'd sub nom. Frei v. Taro Pharm. U.S.A., Inc., 844 F. App'x 444 (2d Cir. 2021), cert. denied sub nom. Frei v. Taro Pharms. (USA) Inc., 142 S. Ct. 766, 211 L. Ed. 2d 480 (2022). Plaintiffs' fourth claim for negligence per se also fails because (1) as discussed herein, Plaintiffs have not plausibly alleged that Aurobindo failed to comply with the Medication Guide requirement, and (2) any claim based on Aurobindo's failure to provide an adequate label is barred by the Supreme Court's holding in PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011), that "manufacturers cannot unilaterally change a generic drug's labeling, and therefore a state-law claim premised on such a manufacturer being obligated to revise its label is preempted." In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II), 751 F.3d 150, 162 (3d Cir. 2014); see, e.g., Jankowski v. Zydus Pharms. USA, Inc., No. 20-CV-202458, 2021 WL 2190913, at *6 (D.N.J. May 28, 2021); see also Frei, 443 F. Supp. 3d at 469. Finally, Plaintiffs' fraud claim, which is subject to Rule 9(b), fails because, among other things, their nearly 100-page complaint does not adequately identify Aurobindo's purportedly misleading statements or omissions, the statements Aurobindo left uncorrected, or how such statements caused Plaintiffs' injuries.

provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Congress may exert its supremacy by expressly preempting state law, but it may also do so implicitly." Sikkelee v. Precision Airmotive Corp., 822 F.3d 680, 687 (3d Cir. 2016) ("Sikkelee I"). Because "Congress has not enacted [an express preemption] provision for prescription drugs," we need only consider whether implied preemption bars Plaintiffs' remaining claims. Wyeth v. Levine, 555 U.S. 555, 574 (2009). One implied preemption basis is "conflict preemption." There are two types of conflict preemption: impossibility preemption and obstacle preemption. Sikkelee v. Precision Airmotive Corp., 907 F.3d 701, 710 (3d Cir. 2018) ("Sikkelee II"). Conflict preemption can occur "when a state law conflicts with federal law such that compliance with both state and federal regulations is impossible, . . . or when a challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law." Sikkellee I, 822 F.3d at 688 (citations and quotation marks omitted).

"[C]ertain state-law claims against manufacturers of generic drugs conflict directly with federal law and are without effect because of impossibility pre-emption." In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II), 751 F.3d 150, 160 (3d Cir. 2014). For example, certain state law failure-to-warn claims against generic drug manufacturers are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., because generic drug manufacturers have a "federal-law duty to keep [their] label the same" as the brand-name's. PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011);

accord In re Fosamax, 751 F.3d at 162-63.[7] Because the generic manufacturer must use the same label as the brand-name manufacturer, it cannot change its label and thus it would be impossible for the generic to change the label to comply with state law. Thus, the FDA duty of sameness preempts any state law duty that would require a generic drug manufacturer to change its label.

The FDCA also "preempts any state-law claim that exists 'solely by virtue' of an FDCA infraction." Plourde v. Sorin Grp. USA, Inc., 23 F.4th 29, 33 (1st Cir. 2022) (quoting Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 353 (2001)). Put differently, if a violation of an FDCA requirement is the basis for a state law claim, then the state law claim is preempted. See id. Thus, where "the existence of the[] federal enactments [is] a critical element in the[] case," such a claim is preempted because such litigation "would exert an extraneous pull on the [regulatory] scheme established by Congress." Buckman, 531 U.S. at 353; see Sikkelee II, 907 F.3d at 716-17 (concluding failure-to-notify-FAA

[7] FDA approval of new drugs (i.e., brand-name ones) and generic drugs generally proceed through two different routes. Entities seeking approval of a brand-name drug must file a New Drug Application ("NDA"), which the FDA will approve "only if it determines that the drug in question is safe for use under its proposed labeling and the drug's probable therapeutic benefits outweigh its risk of harm." Sikkelee I, 822 F.3d at 703 n.20; see 21 C.F.R. § 314.105(c) ("FDA will approve an NDA after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling."). Generic drug manufacturers, by contrast, file Abbreviated New Drug Applications ("ANDA"). Through the ANDA route, "manufacturer[s] of generic drugs can piggyback off of a previously-approved brand-name drug, but [are] required by federal law to match the preapproved brand-name analogue's labeling and composition exactly." Sikkelee I, 822 F.3d at 703 n.20 (emphasis omitted); see 21 C.F.R. 314(c) ("FDA will approve . . . an ANDA after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence."); see also Mensing, 564 U.S. at 613 (explaining the FDA's view that "generic drug manufacturers have an ongoing federal duty of 'sameness'").

claim was preempted, and citing to Buckman, where plaintiff "attempted to use a federal duty and standard of care as the basis for [a] state-law negligence claim").

Mindful of these preemption principles, we will examine the three bases for Plaintiffs' PLA claims, namely Aurobindo's alleged failure to: (1) provide Medication Guides to Plaintiffs or to provide them in sufficient numbers or in proper form to pharmacists or similar entities so as to ensure Plaintiffs received them; (2) disclose adverse medical events connected to the product; and (3) correct certain information on which physicians relied regarding Amiodarone and its side effects. See SAC ¶¶ 112-24.[8]

A[9]

Plaintiffs' Medication Guide theory alleges that Aurobindo's failure to warn stems from its failure to provide Medication Guides. This theory does not provide Plaintiffs a basis for relief for several reasons for several reasons.

[8] One of Plaintiffs strict liability claims is entitled "Strict Liability – Manufacturing Defect." See SAC ¶¶ 149-58. Neither party addresses this claim in their briefing. The absence of any discussion of a manufacturing defect is not surprising as "Plaintiffs' allegations . . . do not sound in defective manufacturing." Jankowski, 2021 WL 2190913, at *5. Instead, this count takes issue with "warnings," "labeling," and Aurobindo's alleged failure "to ensure the Medication Guides were properly printed, affixed, distributed, and received." SAC ¶¶ 153-54; cf. Myrlak v. Port Auth. of N.Y. & N.J., 723 A.2d 45, 52 (N.J. 1999) ("[A] manufacturing defect under the [PLA] occurs when the product comes off the production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing specifications."). Thus, Plaintiffs' manufacturing defect claim simply recasts their failure to warn claim, and it will be treated as such.

[9] Because the Court will dismiss all counts based on either the PLA, preemption, or a failure to state a claim, it need not address Aurobindo's statute of limitations arguments.

First, their Medication Guide claims are preempted. McDaniel v. Upsher-Smith Lab'ys, Inc., 893 F.3d 941, 946 (6th Cir. 2018). The obligation to provide Medication Guides is embodied in the FDCA and related regulations. The FDCA requires manufacturers to provide Medication Guides to distributors, packers, and dispensers for distribution to patients who are prescribed a particular drug. 21 C.F.R. § 208.24(b). A manufacturer can comply with this requirement by either: (1) "[p]roviding Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product," or (2) "[p]roviding the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product." 21 C.F.R. § 208.24(b). In other words, Aurobindo can either provide the Guides to distributors, packers, or authorized dispensers or provide the means to produce them in sufficient numbers. Because a manufacturer need only "ensur[e] that Medication Guides are available for distribution to patients" through those two routes, 28 C.F.R. § 208.24(b), it is not obligated to provide the Medication Guides directly to the patient.

To the extent Plaintiffs allege that Aurobindo violated the PLA by failing to provide the guides to the entities who should have received them, and thus failed to facilitate the delivery of warnings, the violation of the FDCA is a "critical element" of the claim. Buckman, 531 U.S. at 353. Put simply, Plaintiffs' claim exists solely due to the FDCA requirement. Buckman, 531 U.S. at 353; see Frei v. Taro Pharms. U.S.A., Inc.,

443 F. Supp. 3d 456, 468 (S.D.N.Y. 2020), aff'd sub nom. Frei v. Taro Pharm. U.S.A., Inc., 844 F. App'x 444 (2d Cir. 2021), cert. denied sub nom. Frei v. Taro Pharms. (USA) Inc., 142 S. Ct. 766 (2022); see also Sikkelee, 907 F.3d at 716-17. Plaintiffs' attempt to use a state products liability law to seek relief for a violation of this FDCA requirement is preempted under Buckman. 531 U.S. at 353.

Second, to the extent Plaintiffs assert that Aurobindo had a duty under state law to provide Medication Guides directly to the patients[10]—e.g., that the Medication Guide regulation gives rise to an exception to the learned intermediary doctrine[11]—they have failed to identify a New Jersey law that imposes such a duty on a manufacturer like Aurobindo. See Medford, 2021 WL 5204035, at *4 (noting a similar failure); Jankowski v. Zydus Pharms. USA, Inc., No. 20-CV-2458, 2021 WL 2190913, at *4 (D.N.J. May 28, 2021) (same). Furthermore, Plaintiffs' reliance on Perez v. Wyeth Labs, Inc., 734 A.2d 1245 (N.J. 1999), is misplaced. In Perez, the New Jersey Supreme Court held that "the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers." Id. at 1257; Burns v. Bos. Sci. Corp., No. 18-CV-12323, 2019 WL 1238829, at *7 (D.N.J. Mar. 18, 2019) ("[T]he only exception to the learned intermediary

[10] In their brief, Plaintiffs assert that they "never pleaded that manufacturers must provide Medication Guides directly to consumers under federal regulations," Pls.' Br. at 19, but their SAC belies this assertion, see, e.g., SAC ¶¶ 1-16 (subparagraph f), 21, 44, 88, 111, 114, 145, 147.

[11] The learned intermediary doctrine provides that "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Grobelny v. Baxter Healthcare Corp., 341 F. App'x 803, 806 (3d Cir. 2009) (quoting Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989)); see N.J.S.A. § 2A:58C-4.

doctrine arises when a pharmaceutical company has advertised its drug directly to the consuming public."). Stated differently, "[t]he New Jersey Supreme Court recognized that when a drug manufacturer markets their prescription drug directly to the consumer, there is a corresponding duty to warn the consumer." Baker v. App Pharms. LLP, No. 09-CV-05725, 2012 WL 3598841, at *8 n.11 (D.N.J. Aug. 21, 2012) (quoting Perez, 734 A.2d at 1263). Even if the Court assumed that a claim based on such a duty was not preempted, Plaintiffs have not alleged that Aurobindo engaged in such advertising, so Perez is inapt.[12]

[12] The Court, sitting in diversity, is "reluctant to create new rights that neither the state legislature nor the state courts have seen fit to recognize." Nationwide Mut. Ins. Co. v. Buffetta, 230 F.3d 634, 642 (3d Cir. 2000). To adopt Plaintiffs' request to find a duty to warn here may impose a new basis for liability that is contrary to the FDA. Small v. Amgen, Inc., 723 F. App'x 722, 726 (11th Cir. 2018) ("The FDA stated that it '[did] not believe that [the Medication Guide] rule would adversely affect civil tort liability' and that 'the written patient medication information provided [did] not alter the duty, or set the standard of care for manufacturers, physicians, pharmacists, and other dispensers.'" (first and third alteration in original) (quoting Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66378, 66383-84 (Dec. 1, 1998))). The Court declines to do so, particularly because it is not even clear how the Medication Guide regulation fits within Plaintiffs' framework given their position that manufacturers are not required "to provide Medication Guides directly to consumers under federal regulations," Pls.' Br. at 19.

Furthermore, even if the Plaintiffs are correct that drug manufacturers have a duty to warn consumers when the physicians receive inadequate warnings, Plaintiffs have not plausibly alleged that Aurobindo failed to adequately warn them. Plaintiffs cite their adverse event report allegations, but those allegations are inadequately pleaded as discussed herein. See Pls.' Br. at 30 (citing SAC ¶¶ 81-84, 119-21, 163). They also cite vague allegations regarding "misleading 'warnings' or information . . . that watered down the FDA-approved labeling," Pls.' Br. at 30 (citing SAC ¶ 122), which they neither sufficiently attribute to Aurobindo nor adequately describe. Moreover, they have not shown that Aurobindo, as a generic manufacturer, would have the authority to provide a warning that differs from the brand name's label. See Mensing, 564 U.S. at 618 ("Federal law . . . demand[s] that generic drug labels be the same at all times as the

Third, even if Plaintiffs were permitted to bring a claim based upon a violation of the Medication Guide regulation, 21 C.F.R. § 208.24, they have not adequately alleged that Aurobindo failed to comply with it. In their SAC, Plaintiffs allege only that Aurobindo (1) failed to provide Medication Guides to Plaintiffs; see, e.g., SAC ¶¶ 1-16 (subparagraph f), 21, 44, 88, 111, 114, 145, 147; (2) failed to provide enough Medication Guides or failed to provide them "in proper form," see ¶¶ SAC 20, 44, 48-49, 104, 110-11; and (3) failed to ensure Plaintiffs received the Guides, see ¶¶ SAC 1-16 (subparagraph f), 44, 51, 104, 110-11. Under the regulation, Aurobindo is not obligated to provide the Medication Guide to patients. Frei, 844 F. App'x at 447 ("[The pertinent regulation, 21 C.F.R. § 208.24,] does not require that [the manufacturer] distribute Medication Guides, let alone to patients at the point of sale."). Rather, it is only required to provide them, or the means to produce them in sufficient numbers, to distributors, packers, and dispensers. The allegations in the SAC do not address whether Aurobindo provided the relevant entities with the "means" to produce the Medication Guides.[13]

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corresponding brand-name drug labels."). In fact, Plaintiffs seem to recognize this limitation as they have not argued against its applicability in their brief.

[13] The two citations Plaintiffs provide in their briefing to support their assertion that Aurobindo failed to provide the means to produce Medication Guides do not speak to the issue. One citation focuses on whether Plaintiffs received the Guides and whether Aurobindo provided them, neither of which suffices to plausibly allege that Aurobindo failed to comply with § 208.24 because it does not address whether Aurobindo provided the relevant parties the means to do provide Medication Guides. See SAC ¶¶ 1-16 (subparagraph e) (Plaintiff "did not receive the Medication Guide from [his or her] pharmacist because the Medication Guides were not provided by Aurobindo . . . to pharmacists for distribution with [plaintiff's] prescription in sufficient quantities, if at all"). The other states only that "Defendants were responsible for ensuring that appropriate . . . Medication Guide[s] were provided" to Plaintiffs, see SAC ¶¶ 1-16 (subparagraph f), which again says nothing about whether Aurobindo provided the

Although Plaintiffs argue in their brief that Aurobindo failed to provide the "means" to produce the Guides "in proper form," Pls.' Br. at 5, 19, they may not amend their complaint through their briefing. See, e.g., Pa. ex rel. Zimmerman v. PepsiCo, Inc., 836 F.2d 173, 181 (3d Cir. 1988) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." (citation omitted)). Thus, Plaintiffs have not plausibly alleged Aurobindo failed to fulfil its duty to warn by failing to provide Medication Guides.

B

Plaintiffs also assert that Aurobindo failed to report adverse events to the FDA. In support of this contention, Plaintiffs allege, among other things, that "millions of persons . . . are diagnosed with [a-fib] annually," "Amiodarone . . . has become the number one prescribed drug for the treatment of [a-fib]," "[b]ased on the percentages of persons diagnosed just with pulmonary toxicity, there would be tens of thousands o[f] adverse event reports submitted each year," and there "does not appear to be even close to the number of these reports submitted to the FDA in connection with Amiodarone." SAC ¶ 79. Plaintiffs also note an increase in adverse event reporting that "correlat[es]" with "the litigation surrounding Amiodarone." SAC ¶ 84.

Plaintiffs have failed to identify any state law that requires Aurobindo to report adverse events to the FDA, and courts in this District have concluded no such duty exists. See, e.g., In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig., 537 F. Supp.

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relevant parties the means to produce the Medication Guides as required under the § 208.24.

3d 679, 733 (D.N.J. 2021). Instead, the duty Plaintiffs identify appears to be predicated on an obligation created by the FDCA and related regulations. See 21 C.F.R. §§ 314.80, 314.98. Such a claim, however, is preempted under Buckman. See, e.g., Bennett v. Teva Pharms. USA, Inc., No. 19-CV-2126, 2021 WL 797834, at *4 (D. Del. Mar. 2, 2021), appeal docketed, No. 21-1642 (3d Cir. Apr. 9, 2021); see also, e.g., Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1330 (11th Cir. 2017) ("Applying Buckman, [plaintiff's] failure to report theory is impliedly preempted.").

Even if such a duty did exist under New Jersey law, Plaintiffs' general allegations regarding the purported dearth of adverse event reports over the years do not plausibly allege that Aurobindo violated such a duty. Among other things, Plaintiffs—like plaintiffs in other Amiodarone cases cases—have failed to allege "any actual adverse event that [Aurobindo] did not report to the FDA." Medford, 2021 WL 5204035, at *6.[14] Thus, Plaintiffs are not entitled to relief based upon the purported failure to report adverse events.

C

Plaintiffs also seek relief based upon Aurobindo's alleged failure to correct certain information on which physicians relied regarding Amiodarone and its side effects. This

[14] See also, e.g., Jankowski, 2021 WL 2190913, at *5 (noting the same pleading defect in Amiodarone case); Frei, 844 F. App'x at 447 (affirming dismissal of claim premised on failure to report adverse events related to Amiodarone where the plaintiffs' "theory [wa]s based on a broad statistical allegation, and [wa]s not specifically tied to [the manufacturer's] conduct"); see also Nunn v. Mentor Worldwide, LLC, 847 F. App'x 373, 376 (9th Cir.) (affirming dismissal of failure to report adverse events claim where "[p]laintiffs fail[ed] to allege actual adverse events that [the entity] did not report to the FDA"), cert. denied sub nom. Billetts v. Mentor Worldwide LLC, 142 S. Ct. 514 (2021).

claim is preempted under Mensing to the extent that it is premised on an assertion that Aurobindo should have changed its labeling and thereby ensure proper information was contained in physician reference materials. See Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 488 (2013); see also Jankowski, 2021 WL 2190913, at *5.[15]

Even if Plaintiffs' claim was not preempted, Plaintiffs' allegations are insufficient to provide a basis for relief. Plaintiffs do not (1) "allege what th[e] misleading information was or adduce any examples, beyond vaguely asserting that the effect of the reference materials was to "deceive[] physicians into believing" that Amiodarone safely treated [a-fib]," (2) "tailor their allegations to [Aurobindo]," (3) explain, if the reference material—e.g., the information in the Physician's Desk Reference and Epocrates—is "labeling," how Aurobindo, "as a generic manufacturer," had "control over this labeling," (4) "explain what [Aurobindo's] contribution to or authority to correct the reference materials was," or (5) provide a basis to infer from Aurobindo purportedly providing permission to use images of its pills in reference materials that it "controlled the medical content of the reference materials." Frei, 844 F. App'x at 447. Accordingly, this theory does not provide a basis for relief.[16]

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[15] Plaintiffs' arguments and allegations sometimes conflict with respect to Aurobindo's labeling. In their briefing, for example, Plaintiffs state that they "do not seek a label change," Pls.' Br. at 14-15, whereas they allege deficiencies in Aurobindo's labeling in their SAC, see SAC ¶¶ 92-93, 116, 122. Regardless, as already explained, any claim predicated on a view that Aurobindo failed to change its labeling is preempted as its labeling must mirror the brand-name's. See In re Fosamax, 751 F.3d at 163.

[16] Plaintiffs also bring a claim for wrongful death. SAC ¶ 170-75; Pls.' Br. at 35 n.6. A wrongful death claim is barred if it "could not have been asserted by a surviving plaintiff on his or her own behalf." Beim v. Hulfish, 83 A.3d 31, 40 (N.J. 2014);

IV

For the foregoing reasons, Aurobindo's motion to dismiss, ECF No. 27, is granted.

Giardina v. Bennett, 545 A.D. 139, 144 (N.J. 1988). Because all of Plaintiffs' claims must be dismissed, the Court must also dismiss their claim for wrongful death.